UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,642	12/04/2001	Adam Kois	10624-049-999	6698

20583 7590 06/20/2003

PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER	
FORD, JOHN M	

ART UNIT	PAPER NUMBER
1624	11

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/004642	Kox et al
Examiner	**Group Art Unit**
J. M. Ford	1624

—Th MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on May 27, 2003.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1, 2 and 7—38 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 1, 2, 7—10 and 38 is/are allowed.

☒ Claim(s) Claim 11 is is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 12—37 are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)–(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)–(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO–1449, Paper No(s). _____

☐ Interview Summary, PTO–413

☐ Notice of Reference(s) Cited, PTO–892

☐ Notice of Informal Patent Application, PTO–152

☐ Notice of Draftsperson's Patent Drawing Review, PTO–948

☐ Other _____

Office Action Summary

Applicants response of May 27, 2003, is noted.

The claims in the application are claims 1, 2 and 7--38.

Claims 1, 2 and 7--10 are allowed, as is claim 38.

MPEP 806.05 (h) provides for restriction where the compounds may be used for than one purpose. Claims 12--37 indicate that the compounds are alleged to be useful for more than one purpose.

Applicants need to elect one method of use from claims 12--37.

The statement in claim 12, a condition responsive to IKK-2 inhibition does not comply with 35 U.S.C. 112, 1st paragraph. This utility screen does not name a specific disease, this utility screen does not establish a specific utility, as required by Brenner vs. Manson, 148 U.S.P.Q. 689.

The utility statements are too vague to meet the requirements of 35 U.S.C. 12, 1st paragraph.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims , In re Rainer, 146 USPQ 218 (1965); In re Colianni, 195 USPQ 150, Ex parte Forman 230 USPQ 546. Determining if any particular cancer would be treatable with Applicants' compounds would require clinical trials in each disease with each compound. Considering the thousands of

compounds covered by formula I and the multitude of different cancers, this is a very large degree of experimentation.

This requirement to elect one specific disease is consistent with PCT Rule 13.2 and 37 CFR 1.475.

37 CFR 1.475 makes it clear that in addition to the examination of the compounds, applicants are entitled to have one use of their compounds examined therewith, here.

Applicants elected claims 24--27.

Claims 24--27 are not limited to treating inflammation, as elected.

Claims 25--26 are not limited to the compounds of claim 1.

The agreement to examine one specific method of use with the elected compounds is based on the method claim being of the same scope as the compound claim.

Claims 25 and 26 are not of the same scope as claim 1 as they add additional active ingredients.

Claim 11 is rejected under 35 U.S.C. 112, 2nd paragraph; as it does not have the word "pharmaceutical" before composition. Therefore, it is not clear what the purpose of the composition is.

Claim 11 is rejected under 35 U.S.C. 112, 1st paragraph as the specification does not support the use of the composition for all purposes, as is claimed.

John M. Ford:jmr

June 19, 2003

JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624